BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 29/00 — A1

(11) International Publication Number: WO 94/11051

(43) International Publication Date: 26 May 1994 (26.05.94)

(21) International Application Number: PCT/US93/00882

(22) International Filing Date: 3 February 1993 (03.02.93)

(30) Priority data:
07/978,230 19 November 1992 (19.11.92) US

(71) Applicant: TARGET THERAPEUTICS, INC. [US/US]; 47201 Lakeview Boulevard, P.O. Box 5120, Fremont, CA 94537-5120 (US).

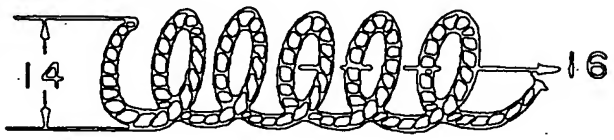
(72) Inventors: CHEE, U., Hiram ; 4151-D El Camino Way, Palo Alto, CA 94306 (US). MARIANT, Mike ; 2169 Ventura Place, Santa Clara, CA 95051 (US). ENGELSON, Erik, T. ; 556 Bush Street, Mountain View, CA 94041 (US).

(74) Agents: CAGAN, Felissa, H. et al.; Morrison & Foerster, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US).

(81) Designated States: AU, CA, FI, HU, JP, KR, NO, NZ, PT, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: LARGE DIAMETER VASOOCCLUSION COIL



(57) Abstract

A device for occluding a large diameter (1 to 3 cm) vessel. The device comprises a helical coil (10) having a multiplicity of windings (14). The helical coil (10) may further be shaped into a variety of structures including a C-shape, a cloverleaf, and a figure 8.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgystan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo			SE	Sweden
CH	Switzerland	KR	Republic of Korea	SI	Slovenia
CI	Côte d'Ivoire	KZ	Kazakhstan	SK	Slovakia
CM	Cameroon	LI	Liechtenstein	SN	Senegal
CN	China	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
CZ	Czech Republic	LV	Latvia	TJ	Tajikistan
DE	Germany	MC	Monaco	TT	Trinidad and Tobago
DK	Denmark	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali	UZ	Uzbekistan
FR	France	MN	Mongolia	VN	Viet Nam
GA	Gabon				

LARGE DIAMETER VASOOCCLUSION COIL

Description

Technical Field

This invention is in the general field of surgical instruments. More particularly, it relates to a vasoocclusion device that can be used in cardiovascular and endovascular procedures.

Background

Vasoocclusion devices are surgical implements that are placed within vessels, typically via a catheter, to block the flow of blood through the vessel. Vasoocclusive coils have been used to occlude vessels in small-diameter, difficult to reach sites. United States Patent No. 4,994,069 provides a vasoocclusive wire that is guided to a vessel that has a diameter of between 0.5 and 6 mm. The patent describes a flexible vasoocclusive wire that is designed to occlude a vessel when the wire is released into the vessel. The diameter of the coiled wire is between about 10-30 mils, the wire itself has an outside diameter of between about 2-6 mils and there are about 4-8 helical windings. For vasoocclusion of a vessel that is 0.5-2 mm, the wire has a preferred length of about 3-6 cm, and for a vessel that is 2-6 mm, the wire has a preferred length of about 5-10 cm.

The above described coils, therefore, are effective to occlude vessels of between about 0.5 and 6 mm which require tortuous path access. Where, however, the vessel is between about 1-3 cm, the coils were

thought to be impractical as they would be too long to be reliable and might occlude neighboring vessels.

Disclosure of the Invention

It is therefore an object of the present invention to provide a vasoocclusive device that can be used to occlude large diameter vessels. The device is a vasoocclusive coil that assumes a linear helical configuration when stretched and a folded convoluted configuration when relaxed. The stretched condition is used in placing the coil at the desired site and the coil assumes its relaxed configuration once the device is so placed.

The vasoocclusive device is a helical coil having a multiplicity of windings between a first and second end wherein the primary coil diameter is between about 0.25 and 1.5 mm and the diameter of the vessel to be occluded is between about 1.0 and 3.0 cm. Once relaxed, the coil may assume a secondary coil diameter approaching that of the selected vessel.

Brief Description of the Drawings

Figs. 1 to 9 are fragmentary elevational views (not to scale) of embodiments of the helical coil of the invention.

In the drawings, like structures are referred to by the same reference numeral.

Modes for Carrying Out the Invention

Fig. 1 depicts one embodiment, generally designated 10, of the helical vasoocclusive coil of the invention. The helical coil 10 will typically be made of a radiopaque material such as platinum, tungsten, gold, stainless steel, or of alloys such as tungsten and platinum. A tungsten-platinum alloy is preferred because

of its strength and toughness. The material desirably is radiopaque and the diameter of the wire will usually b in the range of 0.05 to 0.25 mm. The coil has a multiplicity of individual windings 12. The axial length of the coil will usually be in the range of 0.2 to 100 cm, more usually 0.2 to 40 cm and the diameter of the coil will normally be 0.25 and 1.5 mm, more usually 0.5 to 1.0 mm. The coil will typically have about 40 to 200 windings per cm, more typically about 50 to 130 windings per cm.

The steps in the construction of the vasoocclusion coils of this invention are shown in Figs. 1-3. The coil itself may be formed by wrappings of windings of a fine radiopaque wire thread, preferably 5 to 8 mil (0.13 to 0.20 mm) platinum, tungsten, gold, stainless steel or alloy thread which is available, for example, from California Fine Wire Company (Grover City, CA). The windings are preferably made by wrapping the thread on a spinning mandrel, according to known coil-manufacturing methods. The wire advance on the mandrel is adjusted to produce a single-layer coil with a minimum helical pitch, i.e., in which the windings are closely packed. Typically, the mandrel has a diameter of between about 0.10 and 1.0 mm yielding a coil whose outer diameter is between about 0.25 and 1.5 mm. The soft, flexible coil produced on the mandrel is cut to a desired length of between about 4 and 100 cm after removal from the mandrel.

The coiled wire may then be wound on a larger diameter mandrel to form a helical winding as shown in Fig. 2 whose helix diameter, indicated at 14, is approximately that of the vessel for which the coil is intended. The helical axis is indicated at 16. Thus for a wire designed for vasoocclusion of a vessel of about 1-3 cm, the diameter of this secondary helical winding is

preferably 1-3 cm, respectively. It can be appreciated from the above-mentioned wire lengths and winding diameters, that the wires typically will contain 1-20 helical windings, more typically 4-8 helical windings as illustrated in Fig. 2.

The coil may further be preformed to contain irregularities in the helical winding, such that the coil adopts a folded, convoluted conformation in a relaxed condition as illustrated in Fig. 3. As seen, the irregularities in this embodiment are such as to offset the helical axis (indicated by arrows in the figure) of each winding by 20-40 degrees. The irregularities are preferably made by deforming, as by twisting, the coil in the region of desired bends with the coil on the helical winding mandrel. The coil may treated by heating at about 800°F for about 24 hours for memory retention after it is shaped.

According to an important feature of the invention, the combination of the helical winding and the irregularities in the winding cause the coil to form a randomly shaped, substantially space-filling mass when released into a vessel, as will be illustrated below. In particular, the memory in the coil is effective to return the coil from a stretched, linear condition in which it is advanced through a catheter to a randomly oriented, space-filling relaxed condition as the coil is released from the catheter.

The coil just described may be thought of as having a primary structure formed by the wire wrapping making up the coil, a secondary structure formed by the helical winding of the coil, and a tertiary structure formed by the irregularities in the winding of the coil. It will be appreciated that the random shape of the coil in its relaxed condition can be achieved by other, related secondary structures in the coil, such as a

series of arcs which are interrupted at intervals by bends which orient the arcs in different directions.

In an alternative method of manufacture, the primary helical coil may be wound around a series of mandrels that are held in some uniform configuration to yield the offset helical shape shown in Fig. 3. Multiple coils may be formed in this way and thereafter the coils may be cut to form individual vasoocclusive coils.

The coil is preferably supplied in prepackaged form in a sterile cannula. The cannula straightens the coil during shipment such that it can be placed within a catheter lumen for delivery to the targeted vessel.

A guidewire is inserted such that a catheter can be guided to the targeted vessel. Once the catheter is in place within a vessel, the guidewire is removed and the coil-containing cannula is placed into engagement with the proximal end of the catheter. The coil is then transferred from the cannula lumen into the catheter lumen by exerting force on the proximal end of the coil. The coil is advanced through the catheter to the tissue of interest by means a guidewire or coil pusher that pushes against the proximal end of the coil. Alternatively, water may be injected into the catheter to force the coil through the catheter lumen. The location of the coil may be visualized due to the radiopacity of the helical coil. Once at the site, the coil is plunged from the distal end of the catheter into the targeted vessel.

In an alternative method in which the guidewire remains in place during coil ejection, the coil is supplied in a cannula which is adapted to engage the proximal end of a guidewire. Once the guidewire and catheter are in place, the coil-containing cannula is placed into engagement with the proximal end of the guidewire and the coil is transferred from the cannula

lumen onto the guidewire by exerting force on the proximal end of the coil. The coil is delivered to the targeted site by being pushed with a guidewire, coil pusher or by means of hydraulic injection as described above.

Figs. 1 to 9 show variants of the invention, but for simplicity of explanation, show the shape when the coil is in the catheter lumen (Figs. 1 and 7) and after release of the coil at the targeted site (Figs. 2 to 6, 8 and 9).

Fig. 2 shows a partial side view of the helical coil 10 in its relaxed configuration. Typically the coil 10 will be placed inside the catheter lumen in its linear stretched form (as shown in Fig. 1) until discharged from the end of the catheter at which time the configuration shown in Fig. 2 will be assumed.

Fig. 3 shows another embodiment of a vasoocclusive coil of the invention after it has been released from the end of the catheter. The coil loops back upon itself to form a secondary coil having a tertiary configuration that may substantially fill the vessel to be occluded. Irregularities in the coil windings allow formation of the folded convoluted conformation in the coil's relaxed condition. As seen, the multiple convolutions or irregularities in the embodiment are such as to offset the helical axis (the arrows in Fig. 3) of each winding by 20-40 degrees.

Figs. 4, 5, and 6 each illustrate a different aspect of the invention. Whereas Fig. 3 shows a helical coil that forms a tertiary shape that is circular, Figs. 4-6 show additional coils whose tertiary structures are also useful in the invention. Fig. 4 shows a cloverleaf-shaped vasoocclusive coil, Fig. 5 shows a figure-8-shaped and Fig. 6 shows a C-shaped vasoocclusive coil. The tertiary structures are the relaxed configurations of the

coils after release into th vessel. The devices are introduced as helical coils as shown in Fig. 1 and then assume the shapes sh wn. The maximum helical coil diameters of the coils shown as 20, 22 and 24 are equivalent to the size of the vessel to be occluded, that is 1-3 cm.

Figures 7 and 8 show a vasoocclusive coil such as is described above, but in which irregularities in the helical winding are produced by flattening the wire coil in different directions. This may be accomplished by flattening or squeezing the linear coil 30 in a number of places 32 along the winding at various angles (if so desired) such as is shown in Fig. 7. The coil so formed will have the general appearance shown in Fig. 7 when in its linear configuration. The coil will be in its linear configuration as shown in Fig. 7 during its introduction into the vessel, but will assume the shape shown in Fig. 8 when in its relaxed configuration.

Fig. 9 shows a coil having a primary coil structure as described above, with a helical winding 40 having at least one helical turn whose diameter 42 is the size of the vessel to be occluded. In this variation, the irregularities in the helical winding take the form of continually changing helical diameters forming spirals which are dimensioned to span the cross-sectional area of the vessel.

The coils of the present invention, therefore are useful for occluding vessels in the range of about 1 to 3 cm. Such applications include the occlusion of fistulas of the pulmonary vasculature in the lungs, trauma in the periphery, arteriovenous malformations, heart anomalies and aneurysms.

Modifications of the above-described modes for carrying out the invention that are obvious to those of skill in the fields of medical device design generally,

and vasoocclusion specifically are intended t be within the scope of the foll wing claims.

Claims

1. A vasoocclusive device comprising a primary helical coil having a multiplicity of windings between a first and second end, wherein the diameter of the primary helical coil is between about 0.25 and 1.5 mm and the diameter of the vessel to be occluded is between about 1.0 and 3.0 cm.

2. The vasoocclusive device of claim 1 wherein the helical coil is from about 0.2 to 100 cm in length and has about 40-200 windings per cm.

3. The device of claim 1 wherein the helical coil assumes a secondary helical coil-shaped structure with between about 4-8 windings.

4. The device of claim 3 wherein the diameter of the secondary helical coil-shaped structure is between about 1.0 and 3.0 cm.

5. The device of claim 3 wherein the helical coil assumes a tertiary structure formed by irregularities in the windings of the secondary helical coil-shaped structure.

6. The device of claim 1 wherein the helical coil assumes a secondary cloverleaf-shaped structure.

7. The device of claim 1 wherein the helical coil assumes a secondary figure 8-shaped structure.

8. The device of claim 1 wherein the helical coil assumes a secondary C-shaped structure.

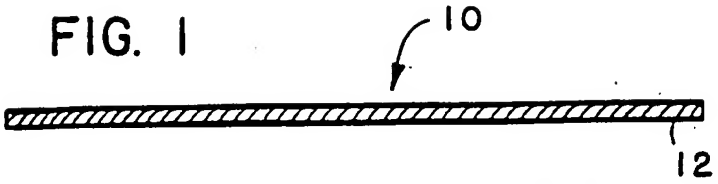
9. The device of claim 1 wherein the helical coil assumes a secondary randomly-shaped structure.

10. The device of claim 9 wherein the randomly-shaped structure forms a substantially space-filling mass when released into the vessel.

11. The device of claim 1 wherein the helical coil assumes a secondary structure of continually changing helical diameters forming spirals.

12. The device of claim 11 wherein at least one spiral is dimensioned to span the cross-sectional area of the vessel to be occluded.

FIG. 1



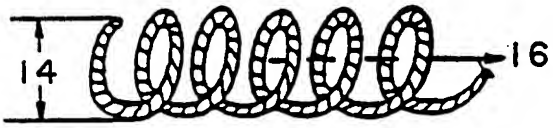


FIG. 2

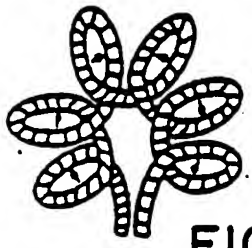


FIG. 3

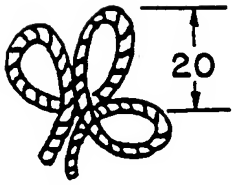
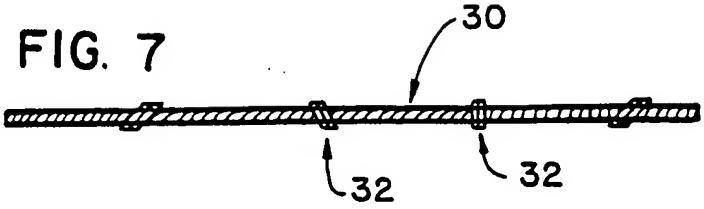


FIG. 4

FIG. 5

FIG. 6

FIG. 7



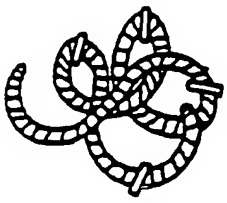


FIG. 8

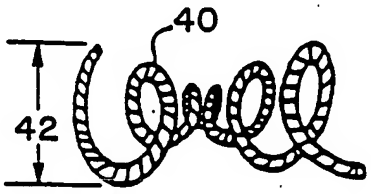


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/00882

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61M 29/00
US CL :606/191

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/108,195,200; 128/898; 623/1,12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US,A, 4,994,069 (RITCHART ET AL) 19 FEBRUARY 1991 See entire document	1-12

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 02 APRIL 1993	Date of mailing of the international search report 21 MAY 1993
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. NOT APPLICABLE	Authorized officer Deanie Goodenough for WILLIAM LEWIS Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet)(July 1992)*